

REMARKS

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request entry of the amendment and reconsideration of the claims.

Claims 1, 3-5, 16, 18-22 and 24-25 are pending in the application.

Claims 1 and 16 were rejected under 35 U.S.C. 102(e) as being anticipated by Easley (US 6,599,271). Applicant traverses these rejections.

It is axiomatic that, to anticipate a claim, a publication must disclose each and every limitation of the claimed invention. Such a disclosure must be clear to one skilled in the art; an Examiner's "interpretation" of a disclosure, particularly when the Examiner reads into the disclosure subject matter that is not in the disclosure, to reject a claim is not proper.

Claims 1, 16 and 20 clearly recite a restrictor having a fixed diameter. Easley, in contrast, only discloses a restrictor having a variable orifice. In fact, Easley recites the "variable" aspect of his orifice not just once, but many times throughout the patent. Further, every embodiment of the device disclosed by Easley teaches a variable orifice. The drawing on the front of the patent, which is the same as Figure 2, shows a restrictor having "an adjustment control 18." The adjustment control is also pictured in Fig. 3; the variable orifice is shown in Figs. 3 and 5. Fig. 8 shows another embodiment using an adjustment means 101. Each of these "adjustment control or means" is finger actuated, and, contrary to the assertion by the Examiner that they are set at the beginning of a procedure and then remain fixed thereafter, are, by their very structure, adjustable at any time.

It is apparent that the Examiner has reached her interpretation because the methods of use of Easley's device set forth in the patent discuss adjusting the adjustment control during set up of the device before a procedure. However, there is nothing structurally that prevents the control from being adjusted at any time during the procedure. Easley in fact recognizes this need: "[T]he desired flow rate, giving the appropriate amount of attraction for the intended surgery, may be obtained using the adjustment 18." Easley, col. 7, ll. 63-65. Moreover, Easley states:

Adjusting the different function valves of the surgery machine for ophthalmic procedures is a balancing act involving many factors influencing the adjustment. Maintenance of the pressure in the anterior chamber of the eye is the controlling factor. However, the maximum pressure allowed in the anterior chamber determines the

maximum pressure setting for irrigation and the maximum flow rate available for irrigation. The aspiration flow setting is determined by the desired amount of attraction to the ultrasound needle. . . The amount of ultrasonic power utilized, coupled with the inside diameter of the ultrasound needle determine the desired maximum vacuum setting. A change in any of the component characteristics used in the procedure can result in changing the usable ranges of all of the function adjustments." *Id.* at col. 3, ll. 35-51.

Given this description in Easley, one skilled in the art would immediately appreciate that the control adjustment of Easley is not meant to be fixed, but that there are advantages available to the surgeon to be able to adjust the flow through the restrictor at any time during a procedure without stopping the procedure should there be a need to so, as with, for example, a cataractuous lens that is harder than initially thought and thus requires additional phacoemulsification energy to fragment. *See, e.g.,* Easley, col. 7, ll. 57-col. 8, ll. 19.

There are significant structural differences between Applicant's invention and Easley's teaching. The restrictor claimed by Applicant in claims 1, 16 and 20, however, cannot be adjusted without stopping the procedure, disconnecting a length of flexible tubing from the restrictor, and replacing a scaling insert within the restrictor, reconnecting the restrictor to the flexible tubing, and restarting the procedure.

Besides the structural differences, the claimed restrictor functions well with both compliant and non-compliant tubing to control post-occlusion surges. Easley himself admits that his restrictor works best when attached to a phacoemulsification handpiece, because such an arrangement eliminates any flexible tubing between the restrictor and the handpiece. Easley states that his restrictor may be placed at a different location, but cautions that "While this embodiment is an improvement over prior art devices, it is susceptible to post occlusion flow surges." Easley, col. 10, ll. 38-39. Easley gives the same caution for the embodiment disclosed in Fig. 8, stating:

I prefer to locate the device in the aspiration tubing 26 as close as practical to the ultrasound handpiece. Again, the length of tubing between the device inlet 91 and ultrasound handpiece 11 can cause

some post occlusion flow surge, because of the change in the internal diameter of the tubing. *Id.* at col. 11, ll. 42-48.

To address this problem, Easley teaches using relatively non-compliant tubing rather than flexible tubing, to reduce this problem. *See* col. 10, ll. 44-47 and col. 11, ll. 48-50.

Claims 3, 5, 18, and 20-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Easley (US 6,599,271). Applicant respectfully traverses these rejections.

The basic problem to be solved is that when an aspiration line of a phacoemulsification system is plugged by debris being suctioned away from the phacoemulsification tip during cataract removal, a large vacuum builds up between the aspiration source and the plug. The typical location of such a plug is within the phacoemulsification handpiece, which is typically connected to the aspiration tube by a length of flexible elastic tubing. The vacuum resulting from the plug is typically sufficient to cause the flexible elastic tubing to collapse. When the plug eventually dislodges, vacuum behind the plug causes a rapid decrease in the pressure at the tip of the phacoemulsification handpiece, which, because it is disposed within a patient's eye during the procedure, results in collapse of the cornea of the eye due to the decreased pressure. Those skilled in art know that such a collapse can result in significant damage to the endothelium of the cornea, leading to increased post-surgical complications.

Easley acknowledges this problem as indicated above. Moreover, Easley states:

An additional cause for pressure change is the elastic nature of the tubing connecting the eye to the vacuum source. The diameter of the tubing changes, based on the pressure difference between the inside of the tubing and atmospheric pressure. That is to say, the tubing becomes smaller as vacuum increases. These diameter changes cause the tubing to store energy, damping pressure changes in the tubing. . . . When the occlusion breaks suddenly, the energy stored in the aspirating tubing causes a surge of fluid to flow, as the tubing returns to the size it was before the occlusion.

Easley, col. 2, ll. 15-29.

Easley consistently teaches throughout his disclosure that use of flexible tubing is detrimental to flow control, and instead discloses using a variable orifice device attached to the

phacoemulsification handpiece in such a manner that all flexible tubing is eliminated between the variable orifice and the handle wherein increases of vacuum cause only insignificant changes in volume between an ultrasound needle tip and the variable orifice. See Easley, Figure 2 and col. 8, ll. 1-33.

In view of Easley's disclosure of the problems associated with the inclusion of deformable tubing between a restrictor device and the handpiece, the unexpected advantages resulting from use of Applicant's claimed inventions coupled to a proximal end of a flexible and resilient aspiration line to prevent collapse of an eye during cataract removal would be apparent to one skilled in the art. First, Applicant's claimed device is designed to be used during intraocular surgery, surgery that requires exceptionally fine control of an ultrasonic handpiece. Eliminating the weight and bulk associated with a restrictor from the handpiece provides for increased mobility and manipulation of the handpiece while reducing surgeon fatigue due to having to hold and manipulate the handpiece. Further, Applicant's claimed invention is advantageous in that it allows use of flexible and resilient tubing, rather than the relatively non-compliant tubing suggested by Easley. As one skilled in the art would immediately appreciate, having a handpiece attached to a length of relatively non-compliant tubing would reduce the maneuverability of the handpiece while increasing the amount of fatigue experienced by the surgeon since it would take additional effort to manipulate the handpiece with the accuracy required to perform delicate intraocular surgery.

As claimed in amended claims 1, 16 and 20, Applicant's claimed flow restrictor having a fixed orifice is coupled to a proximal end of the aspiration tube, and provides a non-linear flow relationship that limits surges in fluid pressure from exceeding a selected maximal flow rate and thus prevents collapse of the eye. None of the prior art, taken alone or in combination, teach or even suggest such a novel combination of features, elements and functions as claimed by Applicant.

For these reasons, Applicant believes that the claimed inventions are neither anticipated by Easley nor obvious in view of the art cited by the Examiner, and no one skilled in the art, even combining the art as suggested by the Examiner, would obtain Applicant's claimed inventions. Accordingly, Applicant respectfully submits that claims 1, 3-5, 16, 18-22, 24 and 25 are patentable over the cited art, and requests that the rejections be withdrawn and the claims allowed.

CONCLUSION

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request entry of the amendment and reconsideration of the claims in view of the remarks presented. In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Should the Examiner have any questions concerning the above amendments and arguments, or any suggestions for further amending the claims to obtain allowance, Applicants request that the Examiner contact Applicants' attorney, John Fitzgerald, at 310-242-2667.

The Commissioner is authorized to credit any overpayment or charge any additional fees in this matter to our Deposit Account No. 06-2425.

Date: February 11, 2008

Respectfully submitted,

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